K073197
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Section 6 – Traditional 510(k) Notification: -Summary

This Traditional 510(k) notification is to provide substantial equivalence for Advanced Medical Solutions Limited's Silver Antimicrobial Wound Gel, which is substantially equivalent to currently marketed devices intended for wound care.

Submitted by:- Advanced Medical Solutions Limited
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United Kingdom

Contact:- Mrs. Claire Ryan
Regulatory Affairs Manager
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Date prepared:- 6th November 2007

Common Name:- Silver Antimicrobial Wound Gel

Trade Names:- Not yet defined

Classification Name:- Dressing, wound, drug

Classification:- Unclassified

Product Code:- FRO

Legally marketed device(s) for substantial equivalence comparison:-
Silver Shield™ Antimicrobial Skin and Wound Gel, 510(k) # K062212, manufactured by Anacapa Technologies, Inc., CA.
AcryDerm Silver Antimicrobial Wound Gel, 510(k) # K011994 and K070333, manufactured by AcryMed Inc., OR also distributed under the trade name SilvaSorb™ Gel, Silver Antimicrobial Wound Gel (Medline Industries, Inc.).

Device Description:-
Silver Antimicrobial Wound Gel is an opaque, amorphous hydrogel containing a high (>80%) water content and hydrophilic polymer chains. This formulation increases the moisture within the wound through water donation which makes the gel effective in assisting the debridement and desloughing process in dry necrotic wounds, whilst maintaining a moist wound environment for optimal wound healing.

Silver Antimicrobial Wound Gel contains an antimicrobial silver compound (silver carbonate) that is an effective barrier to bacterial penetration by inhibiting the growth of broad spectrum of microorganisms which come into contact with the gel.

Silver Antimicrobial Wound Gel is available in various sizes, and is supplied in aluminium tubes fitted with screw caps. The tubes will be packed in a cardboard dispenser box, with a product insert.

Indications for use:-
Silver Antimicrobial Wound Gel is indicated under the medical supervision of a healthcare professional for the management of dry to moderate exuding partial and full thickness wounds such as:

- Pressure ulcers
- Leg ulcers
- Diabetic ulcers
- Graft and donor sites
- Post-operative surgical wounds
- Trauma wounds (dermal lesions, trauma injuries or incisions)
- 1st and 2nd degree burns
- Abrasions and lacerations

Contraindication and Precautions:-
Contraindication: Silver Antimicrobial Wound Gel should not be used on patients with a known sensitivity to Silver or Propylene glycol.
Caution: Frequent or prolonged use of this preparation may result in permanent discoloration of skin and mucous membranes.
Caution: Federal [US] Law restricts this device to sale by or on the order of a physician [or properly licensed practitioner].

Manufacturing:-
Silver Antimicrobial Wound Gel will be manufactured according to the product specification and under good manufacturing practices (GMP). A risk analysis has been performed to identify possible failure mode during manufacturing. Manufacturing controls have been developed and implemented to address the identified risk factors based on the criticality of the failure mode. Advanced Medical Solutions Ltd meets all the established specifications prior to release to ensure the device is safe, effective and correctly labelled for its intended use.

In-vitro Testing:-
The antimicrobial barrier activities of the Silver Antimicrobial Wound Gel have been established by a seven day log reduction evaluation test and preservative efficacy test in accordance with the requirements of USP 30 <51> (Antimicrobial Effectiveness Testing).

In-vitro testing has shown that Silver Antimicrobial Wound Gel is effective against the following broad spectrum of microorganisms; S*taphylococcus aureus,* including MRSA, *Staphylococcus epidermidis,* including MRSE, *Streptococcus pyogenes, Pseudomonas aeruginosa, Escherichia coli* and fungi such as *Candida albicans* and *Aspergillus niger* when they come into contact with the gel. The clinical implications of the in-vitro findings are unknown.

The biocompatibility of Advanced Medical Solutions Ltd. Silver Antimicrobial Wound Gel has been demonstrated to be in compliance with the requirements of BS EN ISO 10993-1 (Biological Evaluation of Medical Devices).

In-vivo Testing:-
Product performance has been established using an *in-vivo* porcine study. The study assessed the dressing performance and compared the Silver Antimicrobial Wound Gel to that of a commercially available equivalent Hydrogel, manufactured by Advanced Medical Solutions which has a similar formulation to the Silver Antimicrobial Wound Gel but contains no silver compound (silver carbonate), and a "Wet to Dry" gauze dressing.

The report findings showed that the rate of wound closure in receipt of Silver Antimicrobial Wound Gel showed no statistically significant differences when compared to the Hydrogel and "Wet to Dry" gauze treatment.

Wound site adherence, though significant in "Wet to Dry" gauze treated wounds, was not detected for the Silver Antimicrobial Wound Gel or Hydrogel at any point in the study – a reflection of the gel structure of these two devices. The surface of wounds in receipt of Silver Antimicrobial Wound Gel was found to include device debris in the form of dark-coloured granules at the day 2 & 4 assessment points; however such granules were not apparent at later time points.

Peri-wound inflammation/erythema was less frequently observed and less severe in Silver Antimicrobial Wound Gel and Hydrogel treated wounds than in similar control "Wet to Dry gauze" treated wounds. No adverse effects were noted following the use of either of the Silver Antimicrobial Wound Gel or the Hydrogel "dressings" investigated.

Statement of Substantial Equivalence:-
The indication for use, performance testing and antimicrobial activity for the Silver Antimicrobial Wound Gel is substantially equivalent to the predicate devices; Silver Shield™ Antimicrobial Skin and Wound Gel, 510(k) # K062212, manufactured by Anacapa Technologies, Inc., CA. and AcryDerm Silver Antimicrobial Wound Gel, 510(k) # KK011994 and K070333, manufactured by AcryMed Inc., OR also distributed under the trade name SilvaSorb™ Gel, Silver Antimicrobial Wound Gel (Medline Industries, Inc.). The biocompatibility and performance testing for the Silver Antimicrobial Wound Gel has demonstrated that the device is safe and effective for the indications of use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 8 2008

Advanced Medical Solutions Limited
% Ms. Claire Ryan
Regulatory Affairs Manager
Road Three, Winsford Industrial Estate
Winsford
Cheshire, CW7 3PD
United Kingdom

Re: K073197
Trade/Device Name: Silver Antimicrobial Wound Gel
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 12, 2008
Received: August 14, 2008

Dear Ms. Ryan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

AUG 2 8 2008

510(k) Number (if known): **K073197**

Device Name: **Silver Antimicrobial Wound Gel**

Indications for Use:

Silver Antimicrobial Wound Gel is indicated under the medical supervision of a healthcare professional for the management of dry to moderate exuding partial to full thickness wounds, such as:

- Pressure Ulcers
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- 1st and 2nd degree burns
- Abrasions and lacerations

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073197